



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/808,677

03/25/2004

Francis C. Wessling, JR.

322101.1030

6200

24504

7590

01/07/2008

THOMAS, KAYDEN, HORSTEMEYER & RISLEY, LLP

600 GALLERIA PARKWAY, S.E.

STE 1500

ATLANTA, GA 30339-5994

EXAMINER

ALI, MOHAMMAD M

ART UNIT

PAPER NUMBER

3744

MAIL DATE

DELIVERY MODE

01/07/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/808,677
Filing Date: March 25, 2004
Appellant(s): WESSLING, ET AL.

MAILED

JAN 07 2008

Group 370C

WESSLING, JR. ET AL
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 09/10/07 appealing from the Office
action mailed 12/12/06

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

NEW GROUND(S) OF REJECTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson (US 4,191,125).

1. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hjertstrand et al. (US 4,145,895) in view of Johnson (US 4,191,125)

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

4,191,125	Johnson	03-1980
4,530,816	Douglas-Hamilton	07-1985
4,145,895	Hjertstrand et al.	03-1979

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-3, 10-12, and 22-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Johnson (US 4,191,125). Johnson explicitly teaches the method and apparatus of a phase change material having a selectable phase change temperature in a range between approximately zero degrees Celsius and 3.8 degrees Celsius (col. 2, lines 57-69) comprising a mixture of water and deuterium oxide (col. 2, line 59) wherein a mole fraction of deuterium oxide is selected to provide a desired phase change temperature (col. 2, lines 57-60), a nucleating agent being added to the mixture (col. 2, lines 38-44), adding a colorant to the mixture (col. 3, lines 12-23), and storing a temperature sensitive material in an environment requiring temperatures between approximately zero degrees Celsius and below 3.8 degrees Celsius (col. 1, lines 5-10 and col. 3, lines 6-23), a pack for holding the phase change material (col. 2, lines 33-37) wherein the pack is shaped to conform for a desired treatment (Figure 1, item 3; "apple" shaped as a freeze indicator), the sensitive material thermally isolated from the environment (col. 1, lines 6-19), and wherein the sensitive material is a biomaterial (col. 2, lines 46-63). Also see column 4, lines 40-42 which reads seventy five percent (75%) of devices froze between 0.5 degree C and -0.5 degree C and the examiner finds it is equivalent to a phase change temperature close to a desired temperature above zero degree Celsius and below 3.8 degree Celsius and thus the above claims anticipated by Johnson.

Regarding claim 1, the phrase, "positioned in close proximity to a biological material such that a temperature of the biological material is maintained near the desired phase change temperature," is the material's intended use, and is not a functional limitation of the material itself, and therefore holds limited patentable weight.

Regarding claim 10, the phrase, "for use in physical therapy in order to maintain live tissue within a desired temperature range," is the material's intended use, and is not a functional limitation of the material itself, and therefore holds limited patentable weight.

Regarding claims 22-27, the biological materials disclosed constitute the material's intended use, and not a functional limitation of the material itself, and therefore holds limited patentable weight.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 4 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson (US 4,191,125) in view of Douglas-Hamilton (US 4,530,816). Johnson teaches the elements of the invention as described above, but fails to teach a gel material added to the mixture. Douglas-Hamilton explicitly teaches a gel material added to the mixture (col. 2, lines 66-67). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the phase change material of Johnson with the gel material of Douglas-Hamilton because adding gel to a thermal mixture increases the thermal capacity of the mixture.

7. Claims 5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hjertstrand et al. (US 4,145,895) in view of Johnson (US 4,191,125)

Hjertstrand et al. explicitly teach placing a temperature depression material (col. 5, lines 17-20, "salt solutions") phase change material (comprising water and deuterium oxide) in close proximity to a sensitive material so that the temperature of the sensitive material is maintained near the temperature of the phase change material (col. 2, lines 66-68 and col. 3, lines 1-10) and providing a container for holding the sensitive material (Figure 1), but fail to teach the mixture of water and deuterium oxide as described above. Johnson explicitly teaches the mixture of water and deuterium oxide as described above, but does not teach a temperature depression material, placing the phase change material in close proximity to a sensitive material so that the temperature of the sensitive material is maintained near

the temperature of the phase change material, or providing a container for holding the sensitive material. placing a temperature depression material (col. 5, lines 17-20, "salt solutions") phase change material (comprising water and deuterium oxide) in close proximity to a sensitive material so that the temperature of the sensitive material is maintained near the temperature of the phase change material (col. 2, lines 66-68 and col. 3, lines 1-10) and providing a container for holding the sensitive material (Figure 1). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the container of Hjertstrand et al. with the phase change material of Johnson because deuterium oxide enables the container to maintain a temperature range of between -4 and 4 degrees Celsius, with the proper mixture determined through experimentation (col. 2, lines 57-65).

NEW GROUND(S) OF REJECTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
8. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson (US 4,191,125). Johnson teaches the invention substantially. However, Johnson does not explicitly teach a range of 0-3.8 degree C as well as limitation of "positioning the phase change mater close to a biological material". But Johnson explicitly encompass and teaches a mixture of 98% deuterium and 2% water which is shown in Example II to have a phase change temperature of -0.5 to 0.5 degree C also referred to as a freezing point of approximately 0 degree C in column 2, lines 65-67. The method and apparatus of a phase change material having a selectable phase change temperature in a range between approximately zero degrees Celsius and below 3.8 degrees Celsius (col. 2, lines 57-69) comprising a mixture of water and deuterium oxide (col. 2, line 59) wherein a mole fraction of deuterium oxide is selected to provide a desired phase change temperature (col. 2, lines 57-60), a nucleating agent being added to the mixture (col. 2, lines 38-44), adding a colorant to the mixture (col. 3, lines 12-23), and storing a temperature sensitive material in an environment requiring temperatures between approximately zero degrees Celsius and below 3.8 degrees Celsius (col. 1, lines 5-10 and col. 3, lines 6-23), a pack for holding the phase change material (col. 2, lines 33-37) wherein the pack is shaped to conform for a desired treatment (Figure 1, item 3; "apple" shaped as a freeze indicator), the sensitive material thermally isolated from the environment (col. 1, lines 6-19), and wherein the sensitive material is a biomaterial (col. 2, lines 46-63).

Johnson discloses the invention substantially as claimed as stated above including devices froze between -0.5 degree C and 0.5 degree C (see column 4, lines 41-42) except the specific steps of method of positioning the phase change material close to a biological material such that a temperature of biological material is controlled by the phase change material. Johnson further indicates in example 1 that these devices were exposed to an environment at -3 degree C. No devices were activated after one hour. However 98% of the devices provided an indication of freeze as described above at -1 degree C. after one hour. 75% of the devices froze between 0-5 degree C and -0.5 degree C. This is obvious that some thing (device) positioning (exposing) to an environment (cooled environment like cooled phase change material) close to the device containing biological material can be kept cool -0.5 degree C. Besides these, it is well known in the art to pack biological material such as blood filled in bags with dry ice which is a phase change material such that a temperature of the biological material (blood) is controlled by the phase change material (dry ice). Thus the method is an obvious implementation of the device. Therefore, it would have been obvious to one of ordinary skill in the art to cool the mixture of deuterium oxide and water to a temperature range of zero to -3 degree C and position it close to a biological material such as blood in order to control the temperature of the biological material.

9. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hjertstrand et al. (US 4,145,895) in view of Johnson (US 4,191,125)

Hjertstrand et al. explicitly teach placing a temperature depression material (col. 5, lines 17-20, "salt solutions") phase change material (deuterium oxide) in close proximity to a sensitive material so that the temperature of the sensitive material is maintained near the temperature of the phase change material (col. 2, lines 66 to column 3, line--10) and providing a container for holding the sensitive material/biological material (blood) with strips 21 packed between thermo blocks 16 made of deuterium oxide close to the biological material (blood) (Figure 1). Placing a temperature depression material (col. 5, lines 17-20, "salt solutions") such as a phase change material (comprising water and deuterium oxide) in close proximity to a sensitive material so that the temperature of the sensitive material is maintained near the temperature of the phase change material (col. 2, lines 66-68 and col. 3, lines 1-10) and providing a container for holding the sensitive material (see Figure 1 of Hjertstrand).

Hjertstrand also teaches using an apparatus to store thermally sensitive biological materials in close proximity to temperature sensitive media to maintain a temperature of 1-6 degree C. However, Hjertstrand et al, do not teach specifically the limitation of mixing the water and selected amount of deuterium oxide to form a phase change material. Johnson explicitly teaches that the mixture of water and deuterium oxide can be cooled to a freeze temperature of zero to -4 degree C (column 2, lines 57-68). Johnson teaches that by varying amounts deuterium and water can get temperatures from -4 to 4 degree C. (see column 2, lines 54-68). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to

combine the container of Hjertstrand et al. to replace thermo blocks 16 with the phase change material of Johnson to comprising with selected amount of deuterium oxide and water as taught by Johnson to maintain temperature of Hjertstrand's temperature sensitive material (biological material) in the disclosed range in order to control the a temperature of the biological material.

(10) Response to Argument.

The Appellant's argument filed on 09/10/07 have been fully considered but they are not persuasive.

A. Summary of the Appellant's arguments.

10-1) On page 5-6 (last Para which continues to page 6) of the Brief the appellant respectfully submits that Johnson fails to disclose "a mixture of water and deuterium oxide wherein the mole fraction of deuterium oxide is selected to provide a desired phase change temperature in a range above zero degrees Celsius and below 3.8 degrees Celsius,".

10-2) On page 6 of the Brief, the appellant stipulates that Johnson does not disclose adding deuterium oxide to water in order to raise the phase change temperature but specifically discloses the range to be between minus (-) 4 degree Celsius and 0 degree Celsius.

10-3) On page 7 (last line and continues to next page 8) of the Brief the appellant states that Johnson fails to disclose "positioning the phase change material close to a

biological material such that a temperature of the biological material is controlled by the phase change material as required by claim 21.”

10-4) On page 10 (Para 3) of the Brief the appellant argues that the final Office action fails to establish that it would have been obvious to combine the select teachings of Hjertstrand with the select teachings of Johnson, and 35 U. S. C. 103 rejection of claim 6 is, for at least this reason, improper.

10-5) On page 9 (last Para) of the Brief the appellant submits that claims 1 and 10 are allowable and further, claims 4 and 13 respectively depend from claims 1 and 10. Thus claims 4 and 13 are also allowable as a matter of law.

10-6) On page 10 (Para 4) of the Brief, the appellant states that Hjertstrand fails to provide any reason or motivation for using a mixture of water and deuterium oxide in lieu of materials specifically suggested therein.

10-7) On page 11 (last portion of Para 1) of the Brief, the appellant asserts that when the cited art is properly considered as whole, it is apparent that one of ordinary skill in the art would not have been motivated to combine the select teachings of Johnson and Hjertstrand, and the 35 U. S. C. 103 rejection of claim 6 is improper for at least this reason.

10-8) On page 11 (last Para) of the Brief, the appellant observes that the material of Johnson does not maintain the specific range of approximately 0-5 degrees.

10-9) On page 12 (last Para) of the Brief, the appellant submits that Johnson teaches away from and, therefore, should not be combined with the teachings of Hjertstrand.

B. Response to the arguments of the Appellant.

10-1B) In response to the appellant's argument contained in the above sub Para 10-1, the Examiner answer is that Column 2, lines 57-68 of Johnson clearly illustrate the fact that deuterium oxide has a normal freezing point of around 4 degrees Celsius and various amounts of water can be added to create a freezing point anywhere from there, all the way down to negative 4 degrees Celsius. As shown by the statements "the freeze point of the mixture may be raised accordingly to accommodate particular needs" in column 2, lines 59-65 and "in order to fine tune the device so that an indication is given for a predetermined temperature, an amount of deuterium oxide may be added to the water," it is clear that the sub range that the appellant provides is within the range of that of Johnson. In addition Johnson discloses that seventy five percent (75%) of the devices froze between 0.5 degree C and -0.5 degree C (see column 4, lines 33-42). Therefore, Johnson does not fail to disclose a mixture of water and deuterium oxide to provide a desired phase change temperature in a range above zero degree Celsius and below 3.8 degree Celsius.

10-2B) In response to the appellant's argument contained in the above sub Para 10-2, the Examiner relies upon the position stated in the sub Para 10-1B and further notes that the claims of Johnson clearly encompass a mixture of 98% deuterium oxide and 2% water which is shown in Example II to have a phase change temperature of -0.5 to 0.5 degree C in column 2, lines 65-67.

10-3B) In response to the appellant's argument contained in the above sub Para 10-3, the Examiner answer is that independent claim 21 is directed to a phase change

material, specifically, and the phrase "positioned in close proximity to a biological material such that a temperature of biological material is maintained near the desired phase change temperature. For claim 21 a new ground of rejections have been set aside with detail explanation in support of the rejections.

10-4B) In response to the appellant's argument contained in the above sub Para 10-4, the Examiner answer is that both Hjertstrand and Johnson Patents are of analogous group as both of them teach biological material and cooling feature. Johnson clearly encompass a mixture of 98% deuterium oxide and 2% water which is shown in Example II to have a phase change temperature of -0.5 to 0.5 degree C in column 2, lines 65-67. Hjertstrand teaches using an apparatus to store thermally sensitive biological material in close proximity to temperature sensitive media to maintain a temperature of 1-6 degree C. Johnson teaches that by varying amounts of deuterium oxide and water can get temperatures from -4 to 4 degree C. It would have been obvious to use a deuterium/water mixture as taught by Johnson to maintain temperature of Hjertstrand's temperature-sensitive material in the disclosed range.

Therefore, appellant's argument that Office action fails to establish that it would have been obvious to combine the select teachings of Hjertstrand with the select teachings of Johnson is not true.

10-5B) In response to the appellant's argument contained in the above sub Para 10-5, The Examiner answer is that claims 1 and 10 are not allowable as explained above and hence on the ground of allowability of claims 1 and 10 their respective dependent claims 4 and 13 are not allowable.

10-6B) In response to the appellant's argument contained in the above sub Para 10-6, the Examiner answer is that Hjertstrand et al. explicitly teach placing a temperature depression material (col. 5, lines 17-20, "salt solutions") phase change material (comprising water and deuterium oxide) in close proximity to a sensitive material so that the temperature of the sensitive material is maintained near the temperature of the phase change material (col. 2, lines 66-68 and col. 3, lines 1-10) and providing a container for holding the sensitive material (Figure 1). This disclosure is proper to combine with Johnson who discloses a mixture of water and deuterium oxide as mentioned above for an obvious rejection to claim 6 because both of the prior art belong to an analogous group. Therefore, appellant's argument that Hjertsrand fails to provide any reason or motivation for using a mixture of water and deuterium oxide in lieu of materials specifically suggested therein is not true.

10-7B) In response to the appellant's argument contained in the above sub Para 10-7, the Examiner answer is that Hjertsrand art explicitly teach placing a temperature depression material (col. 5, lines 17-20, "salt solutions") phase change material (comprising water and deuterium oxide) in close proximity to a sensitive material so that the temperature of the sensitive material is maintained near the temperature of the phase change material (col. 2, lines 66-68 and col. 3, lines 1-10) and providing a container for holding the sensitive material (Figure 1), and Johnson art discloses a mixture of water and deuterium oxide as mentioned above for an obvious rejection to claim 6 because both of the prior art belong to an analogous group. Therefore, appellant's argument that one of ordinary skill in the art would not have been motivated

to combine the select teachings of Johnson and Hjertrand, and the 35 U. S. C. 103 rejection of claim 6 is improper for at least this reason is not correct.

10-8B) In response to the appellant's argument contained in the above sub Para 10-8, the Examiner answer is that Johnson maintains the specific range of approximately between 0.5 degree C and -0.5 degree C (see column 4, lines 40-42) and teaches that one of ordinary skill in the art would be able to vary deuterium oxide and water amounts to yield freezing points from -4 to 4 degree C "to accommodate particular needs" (column 2, line 57 to column 3, line 5) . Therefore, the appellant's argument that Johnson does not maintain the specific range of approximately 0-5 degree is not based on facts.

10-9B) In response to the appellant's argument contained in the above sub Para 10-9, the Examiner answer is that Johnson does not teaches away from the specific teaching needed for 102 and 103 rejections. As clearly mentioned above, Johnson teaches that deuterium/water mixture may be varied depending on the needs of the user. Therefore, the appellant's argument that Johnson teaches away from and, therefore, should not be combined with the teachings of Hjertsrand is not correct.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

This examiner's answer contains a new ground of rejection set forth in section (9) above. Accordingly, appellant must within **TWO MONTHS** from the date of this answer exercise one of the following two options to avoid *sua sponte* **dismissal of the appeal** as to the claims subject to the new ground of rejection:

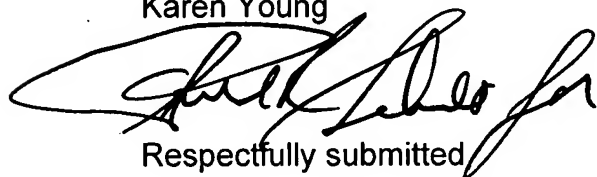
(1) **Reopen prosecution.** Request that prosecution be reopened before the primary examiner by filing a reply under 37 CFR 1.111 with or without amendment, affidavit or other evidence. Any amendment, affidavit or other evidence must be relevant to the new grounds of rejection. A request that complies with 37 CFR 41.39(b)(1) will be entered and considered. Any request that prosecution be reopened will be treated as a request to withdraw the appeal.

(2) **Maintain appeal.** Request that the appeal be maintained by filing a reply brief as set forth in 37 CFR 41.41. Such a reply brief must address each new ground of rejection as set forth in 37 CFR 41.37(c)(1)(vii) and should be in compliance with the other requirements of 37 CFR 41.37(c). If a reply brief filed pursuant to 37 CFR 41.39(b)(2) is accompanied by any amendment, affidavit or other evidence, it shall be treated as a request that prosecution be reopened before the primary examiner under 37 CFR 41.39(b)(1).

Extensions of time under 37 CFR 1.136(a) are not applicable to the TWO MONTH time period set forth above. See 37 CFR 1.136(b) for extensions of time to reply for patent applications and 37 CFR 1.550(c) for extensions of time to reply for ex parte reexamination proceedings.

A Technology Center Director or designee must personally approve the new ground(s) of rejection set forth in section (9) above by signing below:

Karen Young



Respectfully submitted

Conferees:



(1) Baxter Janet C



(3) Mohammad M. Ali

(2) Jules Frantz F

